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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
SMITH, CAROLYN L	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 02/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/954,456	YOUNG, PAUL	
	Examiner	Art Unit	
	Carolyn L Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-35 and 37-52* is/are pending in the application.

4a) Of the above claim(s) *18-35 and 37-50* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17, 51, and 52* is/are rejected.

7)☒ Claim(s) *1,3,9,11-17,51 and 52* is/are objected to.

8)☒ Claim(s) *1-35 and 37-52* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 020420041
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 1/14/04, are acknowledged. Amended claims 1, 2, 4, 6-8, 10-11, 14-15, and 51-52 and cancelled claim 36 are acknowledged.

Applicants state on page 11, line 1 of their Remarks, filed 1/14/04, that claims 1-17, 51, and 52 are pending. This is incorrect. Claims 1-35 and 37-52 are pending; however, claims 18-35 and 37-50 are withdrawn as being drawn to non-elected Groups.

Applicant's arguments, filed 1/14/04, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-17 and 51-52 are herein under examination.

Claim Objections

Claims 1, 3, 9, 11-17, 51, and 52 are objected to due to the inclusion of subject matter which has been non-elected due to a restriction requirement and therefore withdrawn from consideration. The non-elected subject matter in claims 1, 3, 9, 11-17, 51, and 52 is summarized as follows: Claim 1, 3, 9, 11-17, 51, and 52 contain sequences, such as sequences other than SEQ ID NO: 851, 995, 1021, 1062, 1300, 1340, 1483, 1549, 1979, and 2032, which are non-elected subject matter. Removal of non-elected subject matter is requested.

Claim Rejections – 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

LACK OF WRITTEN DESCRIPTION

The rejection of claims 1-17, 51, and 52 is maintained under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time of the invention was filed, had possession of the claimed invention.

The specification discloses SEQ ID NO: 851, 995, 1021, 1062, 1300, 1340, 1483, 1549, 1979, and 2032 which correspond to nucleic acid sequences. SEQ ID NO: 851, 995, 1021, 1062, 1300, 1340, 1483, 1549, 1979, and 2032 and their full complements meet the written description provisions of 35 U.S.C. 112, first paragraph. However, due to the claim language of "expressing a gene that corresponds to a polynucleotide" (claim 1) and "comprising a nucleotide sequence corresponding to a gene" (claim 52), these claims encompass sequences which do not meet the written description provision of 35 U.S.C. 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by these claims.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons

of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of SEQ ID NO: 851, 995, 1021, 1062, 1300, 1340, 1483, 1549, 1979, and 2032, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmacentical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

Therefore, only SEQ ID NO: 851, 995, 1021, 1062, 1300, 1340, 1483, 1549, 1979, and 2032 and their full length complements, but not the full breadth of the claims meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

Applicants point out page 11 (lines 27-31) and page 12 (lines 11-25) where the term "corresponding" is defined to being at least 90% identical to the claimed polynucleotide. This is found unpersuasive as this definition encompasses sequences that are 100% of the claimed sequence plus up to 10% of additional sequence on either end which does not have adequate

written description under 35 USC 112, first paragraph. Applicants note that the claims relate to contacting a cell with a test compound to be evaluated for gene modulating ability which is contained in a cell and such a gene may be part of the genome of the cell and the cell comprises the gene. This is found unpersuasive as these arguments or the amendments to claims 1 and 52 presented by the Applicants do not specifically address the written description rejection, as reiterated above, and is therefore found unpersuasive.

Claim Rejections – 35 U.S.C. 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in *Ex parte Forman*, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in *In re Wands*, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary, (2) the amount or direction presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. The Board also stated that although the level of the skill in molecular biology is high, the results of experiments in genetic engineering are unpredictable. While all of these factors are considered, a sufficient amount for a *prima facie* case are discussed below.

LACK OF ENABLEMENT

Claims 1-17 and 51-52 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the claimed invention.

The sequences selected in these methods include sequences from GenBank with accession numbers AA432248, H18957, AA251010, N71027, AA410986, AA620885, N52026, H98215, T87560, and AA432292. AA432248 is from a human testis, H18957 is from cDNA from a human infant brain, AA251010 is from cDNA from human tonsillar cells, N71027 is from cDNA from fetal liver and spleen, AA410986 is from cDNA from pooled human melanocyte, fetal heart, and pregnant uterus, AA620885 is from cDNA from a human testis, N52026 is from cDNA from a human male with multiple sclerosis lesions, H98215 is from cDNA from a human male melanocyte, T87560 is from cDNA from human fetal liver and spleen, and AA432292 is from cDNA from a human testis. There are millions of sequences in the world with a small portion actually available in public databases, such as GenBank. A microarray type of invention that involves a multitude of elected sequences originating from fetal organs; sex organs; liver, spleen, tonsils, and melanocytes do not appear to be enabling as allegedly (on page 21 of specification) being indicative of differentially expressed in certain types of lung cells for screening chemical compounds for anti-neoplastic activity when the sequences are not from a lung. The EXAMPLE at the end of the specification also fails to provide adequate enablement as there is limited description of what is measured. It is also noted that on the paragraph bridging pages 32 and 33, Applicants confusingly state that only "[a]t least some" of the signature genes display changes in profiles. The quantity of experimentation

required to verify that these sequences represent valid predictors of screening chemical compounds for anti-neoplastic activity as well as which of the particular sequences display changes appears to be undue.

The above-mentioned allegations, on page 21 of the specification regarding the sequences of SEQ ID NO: 1-2276 being broken up into sets where each set of sequences is alleged as being differentially expressed in certain types of cells, are only directed to the concept that certain genes may be differentially expressed between cancer versus non-cancer cells. This does not, however, make it predictable that any of such differentially expressed genes will actually detectably respond when a cell is exposed to an agent being tested for identification of cancer modulating activity as required in the practice of the instant claims. It is also noted that gene expression modulation is an exceedingly complex scientific study and unpredictable regarding the instant invention practice without some specific information directed to responsiveness of any gene for agent testing and identification as instantly claimed.

Due to undue experimentation required, the lack of guidance directed to verifying such sequences functioning as valid predictors, the lack of working examples addressing the same, the unpredictability of knowing if these sequences are potentially valid predictors for screening anti-neoplastic activity, and the breath of the claims; this invention is rejected due to the lack of enablement for one skilled in the art to be able to make and use the invention.

Conclusion

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located

in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The CM1 Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

February 4, 2004

ARDIN H. MARSCHEL
PRIMARY EXAMINER